

1. PURPOSE AND SCOPE

In addition to the preparation and review of documents required by other procedures, High-Level Waste (HLW) Organizations prepare and review other technical and quality assurance documents. This procedure defines responsibilities and actions required to prepare and review selected documents associated with High-Level Waste.

2. REFERENCES

- a. DOE/RW-0333P, Office of Civilian Radioactive Waste Management (RW), Quality Assurance Requirements and Description (QARD)
- b. SPP 2.01, Standard Practice Procedures (SPP) and QARD Requirements Matrix
- c. SPP 3.02, Qualification and Certification Requirements
- d. SPP 4.02, Audits
- e. SPP 4.03, Readiness Reviews and Surveillances
- f. SPP 6.01, Controlled Documents
- g. SPP 7.01, Quality Records
- h. EM Waste Acceptance Product Specifications

3. GENERAL

a. Discussion

Program Manager (PM) is responsible to designate which documents will be prepared and reviewed in accordance with this procedure based on his or her knowledge of the HLW requirements of the respective program. Office Directors or Deputy Directors may also initiate document preparations and reviews in place of Program Managers, but only the PM is designated as the "Performer" in this procedure for purposes of clarity.

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Document(s) specifically within the scope of this procedure are:

- (1) Preparation and review of the EM Waste Acceptance Product Specifications (EM-WAPS) document. Changes to the EM-WAPS require concurrence by RW.

- Rev 4 | (2) Reviews of Operations/Project Office's quality assurance defining documents, such as QARD Requirements Matrix and organization description document. These reviews will include verification of compliance with HLW QA Program Requirements.
- (3) Reviews of HLW QA Requirements for the Fiscal year for Operations/Project Offices.
- (4) Reviews of SPPs and QARD Requirements Matrix (SPP 2.01).
- Rev 4 | (5) Reviews of Waste Form Producer prepared Nonconforming Canister Action Plans. These Action Plans require approval by RW.
- Rev 4 | (6) Reviews of Waste Acceptance process documents including, but not limited to, the Waste Form Compliance Plans (WCP) and Waste Form Qualification Report (WQR). Proposed revisions to these documents shall be forwarded to RW for technical review. RW shall concur on the initial version of a WCP, but not subsequent revisions to it. Subsequent revisions of a WCP shall be forwarded to RW for information and review.
- Rev 4 | (7) Reviews original issuance and revisions to Memorandums of Agreement affecting waste acceptance-impacting activities such as between RW and EM, Project Offices, and other offices, when initiated by EM.

The preparation and review process described by this procedure applies to both new documents and subsequent changes to them. The procedure assigns responsibility for preparer and reviewer assignments and qualifications to the respective PM. This procedure ensures that each Office and technical discipline affected by a document will review it according to established review criteria. The procedure also ensures that the scope and review criteria of the review will be documented prior to the initiation of the review.

b. Definitions

See SPP Glossary of Terms and Acronyms.

4. PROCEDURE

This document shall be used by Headquarters HLW Organizations in preparing and reviewing internal documents and for reviewing those that are prepared by external organizations (example: Operations/Project Offices and M&O/M&I Contractors) and submitted to headquarters for acceptance, concurrence or approval.

a. Preparing Documents**Performer****Action**

PM

- (1) Determines the need to develop or change a document, and assigns a Preparer who is knowledgeable and competent in the subject matter.

Note: Preparer does not participate in review. The Preparer is selected from among HLW personnel, as defined in the Glossary.

Preparer

- (2) Prepares document using review guidance in Attachment A, applicable technical, and regulatory requirements, revision history, and other appropriate documents, as applicable, for input.
- (3) Completes the revision history for the document.
- (4) Upon completion, forwards completed document to the responsible PM.

b. Initiating a Review**Performer****Action**

PM

- (1) Determines that a review is required for a specific technical or quality assurance document.
- (2) Prior to the initiation of the review, prepares a memorandum to identify the scope and review criteria.

Note: In establishing the review criteria, consider applicability, correctness, technical accuracy, completeness, accuracy, and compliance with requirements. Review criteria shall also include applicable elements of the guidance in Attachment A.

- (3) Based on the scope and review criteria, selects reviewer(s).

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Performer

Action

Note: Reviewers shall be other than originators of the document(s), and shall be technically competent in the area being reviewed. Documentation of technical competence shall be maintained in accordance with SPP 3.02.

- (4) Transmits a copy of the memorandum initiating the review to the HLW QAPM, reviewers, and affected organizations.
- (5) Makes available to the reviewer any necessary background information or data that is not readily available to the reviewer.

c. Conducting a Review

Performer

Action

Reviewer

- (1) Reviews document in accordance with the memorandum initiating the review and the guidance in Attachment A.

PM

- (2) Reviews document to ensure that it supports program objectives.

HLW QAPM

- (3) Reviews document to ensure that all QA requirements are adequately covered, including, as appropriate, verification of compliance with HLW Division QA Program requirements.

Reviewer /PM

- (4) Documents review comments on a Review Comment Record (RCR) form similar to Attachment B. RCRs are not required from reviewers if they are the concurring, accepting or approving signatories for the document. Identifies comments requiring mandatory responses on the RCR form.

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d. Resolving Review Comments

<u>Performer</u>	<u>Action</u>
Preparer	(1) Responds to and resolves the review comments. (2) Documents responses to the comments on the RCR Form for resolution with the reviewer.
Reviewer	(3) Documents acceptability or basis for not accepting responses and returns the document to the Preparer. (4) If acceptable comment responses cannot be obtained between the reviewer and Preparer during the resolving comment period of section 4.d.(3), above, the Preparer forwards the comment(s) and their dispositions to the appropriate PM for resolution and closure.
PM	(5) Based on the extent of changes, determines if Reviewer reconsideration is necessary; if reconsideration is necessary, limits review to appropriate PMs only.

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e. Approving EM Headquarters Documents, Except When Addressed by Other Procedures (e.g. SPPs and QA Requirements Matrix)

<u>Performer</u>	<u>Action</u>
Preparer	(1) Upon completion of the review process and resolution of all mandatory comments, forwards the document to the PM.
PM	(2) Reviews and forwards the document to the HLW QAPM for final review. Note: All subsequent changes or revisions to the document shall be submitted to the HLW QAPM even if the changes or revisions do not change the QA requirements.
HLW QAPM	(3) Reviews the final document to ensure that all QA requirements are adequately covered. Forwards the final document to the PM.
PM	(4) Forwards the document to the appropriate level of management for approval.

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Performer

Action

Rev 4 | Appropriate Level of Management (5) Reviews and approves the document and forwards it for distribution. If designated as a controlled document, distributes it in accordance with SPP 6.01.

f. Follow-up, Closure, and Maintenance Actions Specific to HLW Documents

Performer

Action

Rev 4 | PM (1) Appoints a Document Review Specialist to:
(a) Identify, update, and report the status of all unresolved reviewer comments to the Program Manager(s).

Rev 4 | (2) Maintains waste affecting documents, such as the EM-WAPS, current with all applicable source documents.
(3) Closes out all unresolved document review comments prior to any negative impact on the waste acceptance process.
(4) Issues a report or memorandum documenting conclusion of each preparation and review action.

g. Obtain RW Concurrence on specific documents

Performer

Action

PM (1) Forwards documents requiring concurrence by RW, as identified in 3.a., to them for review and comment.
(2) Comments received from RW will be resolved as identified in 4.d. The comments for documents generated by an Operations/Project Office will be returned to the Operations/Project Office for resolution.

h. Records

Performer

Action

HLW QAPM

- (1) Processes the following as nonpermanent records (except for Waste Acceptance Process Documents which are lifetime records) into the central records facility in accordance with 7.01:
 - (a) Documents prepared to this SPP;
 - (b) Correspondence assigning reviewers and preparers, if not covered in the memoranda initiating reviews, except when addressed by other procedures (example: SPPs and QARD Requirements Matrix);
 - (c) Review comments and resolutions documented on RCR forms; except when addressed by other procedures (example: SPPs and QARD Requirements Matrix); and
 - (d) Conclusion report or memorandum.

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5. ATTACHMENTS

Attachment A – Standard Document Review Guidelines

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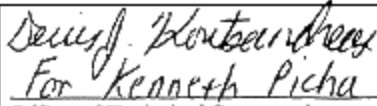
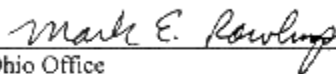
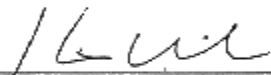
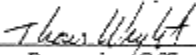
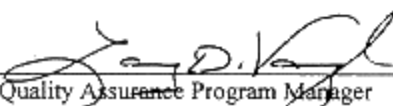
Attachment B – Review Comment Record (Example)

6. REVISION HISTORY

<u>Revision</u>	<u>Description</u>	<u>Effective Date</u>
0	New Procedure	3/24/97
1	Incorporated IC-0-1 and IC-0-2 clarifying review requirements for external QA Program defining documents and requirements for documenting and resolving mandatory review comments.	10/10/97
2	Incorporated IC-1-1, which deleted the requirements to have RCR forms completed by reviewers if the reviewers are concurring, accepting, or approving signatories for the document.	1/8/99
3	Removed QAPD reference; revised approval section per new EM organization; electronic reformatting; addressed internal audit 00-EA-IN-AU-01 issues regarding clarification of “Performers;” minor editorial revisions; added MOAs to list of documents within the scope of this procedure. As this is a major revision, change bars are not retained, in accordance with SPP 2.01, paragraph 4.d.(1).(b).	5/8/00

<u>Revision</u>	<u>Description</u>	<u>Effective Date</u>
4	<p>Incorporated interim change IC-3-1, on page 2, which established consistency between this procedure and the EM/RW MOA, revision 1, appendix C, page C-4, paragraph d. Clarified HLW PM's role in reviewing WCPs and MOAs, at paragraph 3.a.(6) and (7), respectively. Added back note at paragraph 4.b.(2), accidentally dropped in moving from paper to electronic versions of the SPPs (revision 29 to 30). Replaced existing note at paragraph 4.b.(3) with original note. Clarified comment resolution process in paragraph 4.d per reviewer comments. Replaced "quality records system" with "central records facility" at paragraph 4.h.(1). Revised "Office of River Protection" to "River Protection Office" and QAPM approval at section 7. Minor format corrections at sections 4.e.(3), 4.e.(5), and section 5. Removed redundant item "2.15" in attachment A. Minor reformatting at paragraphs 4.b.(2) and (30), and section 7. Deleted "division" from 3.a.(2). Revised "concurrence" to "approval" in 3.a.(5). Added requirement addressing mandatory RCR responses to end of paragraph 4.c.(4). Revised 4.e.(4) to have document forwarded to "appropriate level of management;" and revised performer of 4.e.(5) to "appropriate level of management." Revised performer of 4.f.(1) to "PM." Deleted 4.f.(1).(b). Deleted the performer of 4.f.(2) and generalized this paragraph to "waste-affecting documents." Deleted redundant performer at 4.f.(3).</p>	See SPP Index

7. CONCURRENCE AND APPROVAL

	 For Kenneth Picha Office of Technical Program Integration Office of Integration and Disposition	<u>12/21/00</u> Date
	 Ohio Office Office of Site Closure	<u>12/21/00</u> Date
	 Savannah River Office Office of Project Completion	<u>12/21/2000</u> Date
Rev 4	 River Protection Office Office of Project Completion	<u>12/19/00</u> Date
Rev 4	 Quality Assurance Program Manager	<u>12/22/00</u> Date

ATTACHMENT A

STANDARD DOCUMENT REVIEW GUIDELINES

These standard review guidelines are used as applicable to determine the acceptability of the document. These guidelines do not require that written answers be provided and is not part of the document history file.

**1.0 REVIEW GUIDELINES FOR HLW MANAGEMENT DOCUMENTS
(such as the HLW QA Program Requirements for Fiscal Year for the
Operations/Project Offices, and Memorandums of Agreement.)**

- 1.1 Does any change to existing policy expressed in the document represent a required and appropriate decision?
- 1.2 Are the purpose and scope of work clearly specified?
- 1.3 Are processes as direct and simple as feasible? If the document addresses a management approach or methodology, is the approach as simple and effective as any readily available alternative?
- 1.4 Are the activities, documents, materials, or data, and the individuals or organizations to which the document applies, adequately described?
- 1.5 Are all positions or organizations responsible for implementing the document delineated?
- 1.6 Are management and administrative impacts acceptable?
- 1.7 Are the responsibilities clearly described and in accordance with established organizational divisions of responsibility, or as established in approved procurement documents?
- 1.8 Can the requirements described in the document be implemented?

ATTACHMENT A (Continued)

- 1.9 Are terms defined adequately to ensure consistent interpretation of the document?
- 1.10 Are all the supporting details necessary and sufficient?
- 1.11 Does the document use the required content and format?
- 1.12 Do the exhibits contain the minimum required information?
- 1.13 Are all the exhibits and attachments consistent with the document being reviewed?
- 1.14 Does the proposed change conflict with a previously implemented requirement?
- 1.15 Do the requirements of this document conflict with those of other documents?
- 1.16 Is the document user-friendly, or could it be further simplified or reorganized into a more consistent, logical order?
- 1.17 Does the document avoid elevating administrative convenience to a requirement level?

2.0 REVIEW GUIDELINES FOR HLW TECHNICAL DOCUMENTS (such as the EM-WAPS)

- 2.1 Are document sources appropriate, current, correct, and useable? Do they meet applicable requirements?
- 2.2 Are any assumptions used in the development of the technical document stated explicitly? Are they reasonable?
- 2.3 Is document content consistent with established HLW objectives?

ATTACHMENT A (Continued)

- 2.4 Is the approach compatible with HLW objectives and constraints and with prescribed systems engineering requirements?
- 2.5 Are calculations sufficiently detailed such that a technically qualified person can understand the analysis without requiring outside information?
- 2.6 Have the computer programs required by the technical document been verified?
- 2.7 When applicable, are potential interactions with other technical work addressed adequately?
- 2.8 Are analytical and technical approaches and results reasonable and appropriate?
- 2.9 Does the final document correctly incorporate technical input? Is there adequate, complete, accurate, and traceable flow of requirements from source documents to the final document?
- 2.10 If referenced standards contain conflicting requirements, is the requirement that governs designated?
- 2.11 For input documents, are the following requirements evident: Basic functions of items, performance, regulatory, technical, security, and safety?
- 2.12 Are applicable interfaces identified and documented, such as for work performed in sequence or for product received from another affected organization?
- 2.13 Are the responsibilities for interface requirements delineated?
- 2.14 If there are any constraints on required interfaces, are they described adequately?

ATTACHMENT A (Continued)

- 2.15 Are any unverified portions of the documents clearly identified?
- 2.16 Are units of measure consistent, compatible, and appropriate?
- 2.17 Does the document contain qualitative and quantitative data, and if so, are any necessary tolerances and parameters provided for this data?

**3.0 REVIEW GUIDELINES FOR QUALITY ASSURANCE DOCUMENTS
(such as Quality Assurance Program Descriptions and Standard Practice Procedures)**

- 3.1 Are specified responsibilities and authority consistent with HLW policy or other applicable requirements?
- 3.2 Does the document provide for QA involvement?
- 3.3 Are terms that are defined used in a context consistent with established definitions?
- 3.4 Are all quality records to be generated during the implementation of the document identified and correctly classified? Is the procedure for handling those quality records identified?
- 3.5 Do the processes and controls defined: adequately, completely, accurately, and correctly address the applicable QA requirements?
- 3.6 Is the item or activity to which the document applies clearly identified?
- 3.7 Is there adequate traceability of information used as input to the document?

ATTACHMENT A (Continued)

- 3.8 Are methods for qualifying any unqualified input specified? Is qualification to be tracked?
- 3.9 Are the applicable requirements of the source documents incorporated into the document?
- 3.10 Does the document include or reference appropriate quantitative and qualitative acceptance criteria for determining that prescribed processes have been satisfactorily accomplished?
- 3.11 Are adequate, complete, and correct technical requirements identified including drawings and specifications; codes, standards, and regulations; technical acceptance criteria; and traceability requirements, where appropriate?
- 3.12 Are the technical and quality assurance program deliverables, including QA records, required to be generated and submitted completely and clearly specified?

4.0 REVIEW GUIDELINES FOR HLW EXTERNAL DOCUMENTS (such as the Waste Compliance Plan (WCP) or the Waste Form Qualification Records (WQR)).

- 4.1 Is the document content consistent with applicable regulatory requirements?
- 4.2 Does the document content affect existing regulatory or other external commitments and is it consistent with such commitments?
- 4.3 If the document makes any commitment or addresses a topic of regulatory interest, is it consistent with HLW policy?

ATTACHMENT A (Continued)

- 4.4 If the document will meet a formal submittal requirement, does format and organization of material comply with submittal requirements?
- 4.5 Is there any contradiction between the document, DOE orders, regulatory requirements or commitments?

ATTACHMENT B

REVIEW COMMENT RECORD (EXAMPLE)

REVIEW COMMENT RECORD (RCR)			Page 1 of
Document Reviewed (Title, Number, Revision No./Date)	Reviewer: Reviewed by: _____ Date Organization/Phone No. _____	Dispositioning Organization Representative: Dispositioned by: _____ Date: Organization/Phone No. _____	
Comment	Disposition	Mandatory Comment Y/N	
Comments Satisfactorily Resolved			
Review Signature _____ Date _____			

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TECHNICAL AND QA DOCUMENTS

ATTACHMENT B (CONTINUED)

REVIEW COMMENT RECORD (RCR) CONTINUATION SHEET		Page of
Document Reviewed (Title, Number, Revision No./Date)		
Comment	Disposition	Mandatory Comment Y/N